Supreme Court, U.S.
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NO.___

IN THE SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1993

JEWISH MEMORIAL HOSPITAL, ET AL.,

Petitioners,

v.

COMMONWEALTH OF MASSACHUSETTS, ET AL.,

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME JUDICIAL COURT FOR THE COMMONWEALTH OF MASSACHUSETTS

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103 pp

QUESTION PRESENTED

Whether the Supreme Judicial Court for the Commonwealth of Massachusetts erred in declaring that the Massachusetts Department of Public Welfare's Medicaid regulations governing preadmission screening and level of care do not violate federal utilization review requirements prescribed by Title XIX of the Social Security Act.

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PETITION FOR A WRIT OF CERTIORARI
TO THE SUPREME JUDICIAL COURT
FOR THE COMMONWEALTH OF MASSACHUSETTS

The Jewish Memorial Hospital and Rehabilitation Center, Youville Rehabilitation and Chronic Disease Hospital, New England Sinai Hospital, St. John of God Hospital, Lawrence J. Kerzner, M.D., Henry H. Cho, M.D.,

Lawrence S. Hotes, M.D., and John A. Bolzan, M.D. petition for a writ of certiorari to review the judgment of the Supreme Judicial Court of the Commonwealth of Massachusetts.[1] Respondents are the Commonwealth of Massachusetts, the Massachusetts Division

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[1] Other parties who were appellants in the proceeding in the Supreme Judicial Court are the Massachusetts Respiratory Hospital, Middlesex County Hospital, Shaughnessy-Kaplan Rehabilitation Hospital, Worcester County Hospital, Mehbooba Anwar, M.D., David J. Takvoryan, M.D. and Ronald J. Pantano, M.D.

of Medical Assistance,[2] Bruce M. Bullen, as he is the Commissioner of the Division of Medical Assistance[3] and the Massachusetts Department of Public Health.

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[2] Pursuant to House Bill No. 5090, the Division of Medical Assistance was created to assume responsibility for the Medical Assistance (Medicaid) program for which the Department of Public Welfare had previously been responsible. House Bill No. 5090 was a reorganization bill submitted by the Governor to the General Court. Pursuant to Article LXXXVII of the Amendments to the Massachusetts Constitution, the Bill became effective July 17, 1993.

[3] At the time the lawsuit was filed in Superior Court, Carmen Canino Siegrist was the Commissioner of the Department of Public Welfare and Bruce M. Bullen was the Associate Commissioner.

OPINION BELOW

The opinion of the Supreme Judicial Court for the Commonwealth of Massachusetts (Appendix, infra, A-1 - A-29) is reported at 416 Mass. 132 (1993) and 617 N.E.2d 598 (1993).

JURISDICTION

The judgment of the Supreme Judicial Court for the Commonwealth of Massachusetts was entered on August 11, 1993. A petition for rehearing was denied on September 23, 1993. (Appendix, infra, A-30 - A-31). The jurisdiction of this Court is invoked under 28 U.S.C. §1257.

STATUTES AND REGULATIONS

The Commonwealth of Massachusetts' Medicaid regulations challenged in this case, 106 Code Massachusetts Regulations (CMR) Sections 435.401 and 435.409 to 435.410 effective March 1, 1991, the relevant provisions of the federal Medicare and Medicaid Acts, specifically, 42 U.S.C. §§1395x(k), 1396a(a)(30)(A), 1396b(g)(6)(A), 1396b(i)(4), 1396n(b), 1320c-1, 1320c-3(a)(1), 1320c-7, and the federal Medicare and Medicaid regulations, specifically, 42 C.F.R. §§482.30, 462.104(d), are reproduced in the Appendix (infra, pp. A-32 - A-61).

STATEMENT OF THE CASE

This case involves a challenge under the federal Medicaid statute, 42 U.S.C. §1396b(i)(4) and 42 U.S.C. §1396n(b), to regulations adopted by the Commonwealth of Massachusetts Department of Public Welfare prescribing "level of care" criteria to be applied to determine the medical necessity and appropriateness of placement of Medicaid patients in chronic disease and rehabilitation hospitals. The text of the regulations at issue is contained at Appendix, A-32 - A-47.

The Supreme Judicial Court incorrectly held that the Department of Public Welfare's preadmission screening regulation and level of care criteria did not violate federal utilization review requirements. The Supreme Judicial Court's decision permits the Commonwealth

of Massachusetts to bar Medicaid patients from admission to chronic disease and rehabilitation hospitals in instances where physician members of the hospitals' utilization review committees determine the admission to be medically necessary. Under the level of care regulations and preadmission screening program, the Department of Public Welfare applies standards and procedures, that are inconsistent with those applicable to the Medicare program, to determine whether the admission is reimbursable under the Medicaid program. The Department has not sought or received permission from the Secretary of Health and Human Services to employ utilization review standards or procedures which deviate from Medicare utilization review requirements.

Procedural Background

On November 26, 1990, petitioners commenced this action against the respondents in the Superior Court Department of the Trial Court for the Commonwealth of Massachusetts. The petitioners sought declaratory and injunctive relief. Among other things, the complaint alleged that the Department's regulations governing the Medicaid program for chronic disease and rehabilitation hospitals including the preadmission screening program violated federal utilization review requirements, including 42 U.S.C. §1396b(i)(4) and the waiver provision in 42 U.S.C. §1396n(b). The petitioners moved for partial summary judgment and the respondents moved for summary judgment on all claims. On June

18, 1991, the Superior Court issued summary judgment in favor of the respondents on all claims. On May 1, 1992, the Superior Court issued a declaratory judgment which stated, among other things, that the Department's regulations did not violate the requirements of 42 U.S.C. §1396b(i)(4).

The petitioners appealed from the Superior Court's judgment to the Appeals Court of the Commonwealth of Massachusetts. The Supreme Judicial Court for the Commonwealth of Massachusetts, on its own initiative, accepted the case for direct appellate review. On August 11, 1993, the Supreme Judicial Court ruled, in relevant part, that the preadmission screening regulation does not concern federal utilization review requirements by its

terms and that the level of care regulations fall within the Department's authority to perform utilization control under 42 U.S.C. §1396a(a)(30)(A). Jewish Memorial Hospital, 416 Mass. 136-137, 139, 617 N.E.2d 602-603. The petitioners filed a Petition for Rehearing which was denied on September 23, 1993.

The Medicaid Program

In 1965, Congress established the Medicaid Program as Title XIX of the Social Security Act, 42 U.S.C. §§1396, et seq., to provide federal financial assistance to states that choose to reimburse the cost of medical care for certain indigent persons. States participating in the Medicaid program must operate under a state plan that has been approved by the Secretary of Health

and Human Services ("the Secretary") as conforming with federal requirements. 42 U.S.C. §§1396a(a), 1396a(b).

Under federal law, Medicaid reimbursement is mandated for a hospital placement which is medically necessary. See 42 U.S.C. §1396 (Federal Medicaid program enables states to provide medical assistance "to meet costs of necessary medical services"). See also 42 U.S.C. §§1396a(a)(10)(A), 1396d(a)(1) (State must provide coverage for inpatient hospital services). The Massachusetts State Plan provides for coverage of inpatient hospital services.

"Utilization review" is the process which determines whether patient care services are medically necessary. It involves considerations of whether patient care is appropriately provided at

different "levels of care," such as, in a hospital, nursing home or other setting. See 42 U.S.C. §1395x(k), 42 C.F.R. §482.30 [Medicare] and 42 U.S.C. §1396b(i)(4) [Medicaid]. To determine whether inpatient hospital services are medically necessary and therefore reimbursable under the Medicaid program, federal law requires that a physician certify that the admission is medically necessary at the time the Medicaid patient is admitted. 42 U.S.C. §1396b(g)(6)(a).

Federal law requires that the same utilization review standards and

procedures govern the Medicare[4] and Medicaid programs. Specifically, 42 U.S.C. §1396b(i)(4) provides that utilization review for Medicaid patients be performed "with the same standards and procedures and the same review committee or group" as exist under the Medicare program. Under the Medicare program, hospital utilization review committees are composed of two or more physicians (with or without participation of other professional personnel) who are responsible for determining the medical necessity of services furnished by the hospital. 42 U.S.C. §1395x(k), 42 C.F.R.

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[4] The Medicare program is a program of health care insurance administered by the federal government for individuals sixty-five years of age and older and certain disabled persons. 42 U.S.C. §1395, et seq.

§482.30. Their determinations are subject to review only by a federally approved peer review organization (PRO). 42 U.S.C. §1320c(1) and (7) and 42 U.S.C. 1396b(i)(4). PROs are comprised of licensed doctors of medicine who are authorized to review services provided to Medicare recipients to determine whether they are medically necessary, consistent with professionally recognized standards of care, and furnished in an appropriate setting. 42 U.S.C. §§1320c-1, 1320c-3(a)(1).

Under §1396b(i)(4), the state may not deviate from the utilization review standards and procedures prescribed by the Medicare program "unless the state has demonstrated to the Secretary of Health and Human Services that it has developed a superior method and the

Secretary has waived the requirements of §1396b(i)(4)." The record in this case is clear that the Department did not apply for a waiver or demonstrate to the Secretary that it has developed a superior system. A federal regulation provides that a state Medicaid agency, such as the Massachusetts Department of Public Welfare is "considered incapable of performing utilization and quality review functions in an effective manner, unless the state demonstrates to the satisfaction of HCFA [the Health Care Financing Administration] that it will act with complete independence and objectivity." 42 C.F.R. §462.104(d). The state made no demonstration to HCFA under this regulation.

The Level of Care and Preadmission Screening Regulations

The level of care and preadmission screening regulations conflict with the utilization review standards and procedures applied under the Medicare program. An uncontroverted physician affidavit contained an exhibit which showed the inconsistencies between the utilization review standards and procedures under the Department's regulations and the utilization review standards and procedures applied under the Medicare program. Specific examples of how the regulations violate federal utilization review requirements are set forth below.

Under the level of care regulations at issue, "the Department or its agent", applies the level of care criteria in §§435.409 and 435.410 "to determine the medical necessity and appropriateness of placement" in a chronic disease and rehabilitation hospital. Under the preadmission screening program at section 435.401(B) the Department or a hospital with delegated status is required to apply the level of care criteria to establish whether there is a need for hospitalization prior to admission. Under sections 435.401(B) and 435.409(A)(1) of the regulations, the Department will pay for services only if it or its designated agent has approved a patient admission by applying the level of care regulations. In contrast, under federal law, such determinations are made

by physician members of a hospital's utilization review committee. 42 U.S.C. §1395x(k), 42 C.F.R. §482.30.

The level of care criteria provide a mechanical checklist method for determining the medical necessity and appropriateness of placement. Under section 435.409(A)(1)(c), a patient must require "daily or more frequent physician supervision" or "the constant availability of medical services and equipment ordinarily available only in a hospital setting." The record contains uncontroverted affidavits submitted by physicians who attested that many patients who would not meet these standards would be placed at serious risk by being denied admission to the hospital.

Section 435.409 provides that "the [Department's] evaluator shall use as a guide the Adult Appropriateness Evaluation Protocol [AEP]" in applying the "general criteria" listed under section 435.409(A)(1). Under the federal Medicare program the AEP is not referenced in any rule or regulation. There were uncontroverted affidavits submitted by physicians which stated that under the Medicare program, the AEP is used as a guide by nurse reviewers to approve but never to deny a patient admission to a hospital. Also, the AEP is not used by physicians who rely upon their knowledge of generally accepted medical practice and the actual availability in non-hospital settings of medical resources required by the patient.

The affidavits submitted by physicians stated that if the criteria in the Department's regulations were followed by hospital utilization review committees, their decisions regarding the appropriateness of Medicaid patients' admissions would be different than the decisions mades under the Medicare utilization review process.

Under section 435.409(A)(2) the Department has the authority to override the level of care criteria contained in section 435.409(A)(1) if its own clinical staff makes a determination that chronic disease and rehabilitation hospital care is more cost effective and that the patient's complex medical condition prevents an alternative placement. Under federal law only a PRO is authorized to review determinations made by a

hospital's utilization review committee. 42 U.S.C. §1395x(k). In effect, the Department is functioning as a PRO without the authority to do so. 42 C.F.R. §462.104(d).

REASONS FOR GRANTING THE WRIT

I. CONGRESS HAS MANDATED UNIFORM UTILIZATION REVIEW STANDARDS AND PROCEDURES FOR THE MEDICAID AND MEDICARE PROGRAMS

The decision of the Supreme Judicial Court of Massachusetts conflicts with the federal statutory requirement that utilization review for Medicaid patients be performed "with the same standards and procedures and the same review committee or group as exist under the Medicare program." 42 U.S.C. §1396b(i)(4). Congress has established in 42 U.S.C. §1396b(i)(4) principles for nationally uniform utilization review standards and procedures for the Medicaid program. These principles are important because they ensure that a determination as to

whether a Medicaid recipient requires an inpatient hospital placement will be made by physicians based on medical necessity and professionally recognized standards of care. The writ of certiorari should be granted because the Massachusetts regulations at issue in this case establish utilization review standards and procedures which conflict with federal standards and procedures and interfere with hospitals' and physicians' ability to admit and provide treatment to Medicaid patients.

Congress has a legitimate concern that the two principal health care benefit programs which it funds (Medicare and Medicaid) use the same standards to determine whether services are considered medically necessary and therefore reimbursable. Nationwide, millions of

individuals are covered by state Medicaid programs. If each state is allowed to develop its own standards of utilization review, then Congress' mandate of uniform standards will be undermined.

The lack of uniform standards will result in different coverage decisions based solely on whether the patient's hospitalization is being paid by the Medicare or Medicaid program. Conflicting state and federal utilization review requirements will be particularly harmful in the area of patients dually eligible for Medicare and Medicaid. A dually eligible patient may find himself/herself in the untenable situation where Medicare concludes that inpatient hospitalization is medically necessary but Medicaid reaches the opposite conclusion. The result may be

the denial by the state Medicaid program of payment for Medicare coinsurance and deductible amounts, amounts which Congress has mandated that state Medicaid programs cover if medically necessary. 42 U.S.C. §1396a(a)(10)(E). Congress sought to prevent such a scenario by directing that the same utilization standards be used for both programs.

II. THE SUPREME JUDICIAL COURT'S RULING THAT PREADMISSION SCREENING DOES NOT CONCERN UTILIZATION REVIEW IS CONTRARY TO FEDERAL REGULATIONS GOVERNING THE MEDICAID PROGRAM.

The Supreme Judicial Court erred in ruling that "[p]readmission screening" ... does not concern utilization review by its terms." Jewish Memorial Hospital, 416 Mass. 139, 598 N.E.2d 603. Under the Medicare and Medicaid programs, utilization review encompasses

preadmission review. The federal regulation 42 C.F.R. §482.30 entitled "Condition of participation: Utilization review" governs review of services provided to patients entitled to benefits under the Medicare and Medicaid programs. Section 482.30(c)(1)(i) requires the hospital utilization review plan to provide for review of the medical necessity of "admissions" to the hospital. Section 482.30(c)(2) provides that "[r]eview of admissions may be performed before, at, or after hospital admission." Preadmission screening is a review of the medical necessity of an admission before a patient is admitted to the hospital. Under the federal regulation, 42 C.F.R. §482.30 utilization review includes preadmission review.

III. THE SUPREME JUDICIAL COURT'S DISTINCTION BETWEEN LEVEL OF CARE REGULATIONS GOVERNING PLACEMENT FOR REIMBURSEMENT PURPOSES AND PLACEMENT FOR MEDICAL NECESSITY PURPOSES CONFLICTS WITH THIS COURT'S OPINION IN BLUM V. YARETSKY.

The Supreme Judicial Court incorrectly ruled that the level of care criteria, 106 CMR §§435.409 and 435.410, "concern the question whether a placement in a chronic disease hospital is appropriate for reimbursement purposes" rather than whether placement in such a hospital is medically necessary, citing the federal utilization control statute, 42 U.S.C. §1396a(a)(30)(A) as authority for its ruling. Jewish Memorial Hospital, 416 Mass. 136-137, 598 N.E.2d at 602-603. This distinction between level of care regulations governing placement for reimbursement purposes and

placement for medical necessity purposes is nonexistent under federal law. Under federal law, reimbursement is not simply appropriate but is mandated for an inpatient hospital placement which is medically necessary where coverage for inpatient hospital services is included in the state plan.

As this Court noted, under the Medicaid program, a patient must meet two conditions to obtain financial assistance. S/he must meet eligibility criteria defined in terms of income and resources and s/he must seek medically necessary services. Blum v. Yaretsky, 457 U.S. 991, 1006 (1982), 42 U.S.C. §1396. Federal law is clear that the physician, not the state agency in charge of the Medicaid program, is to certify that hospital services are medically

necessary at the time the Medicaid patient is admitted. 42 U.S.C. §1396b(g)(6)(A). Contrary to federal law, under the Department's regulations the state either makes the determination or controls the determination by establishing the standards to be applied.

Medical necessity determinations are identical to level of care determinations. Corcoran v. United Healthcare, Inc., 965 F.2d 1321, 1332 (5th Cir. 1992), cert. denied, _U.S._, 113 S. Ct. 812 (1992) (utilization review organization makes medical decisions in deciding what benefits are available).

The authority to perform utilization control is not the same as the authority to perform utilization review, i.e., to make medical necessity determinations. The latter has been delegated by Congress

in 42 U.S.C. §1395x(k)(2) to physician members of hospital utilization review committees, subject to review only by the PRO. To comply with utilization control requirements, the state is required to show that a hospital physician has certified the need for inpatient services at the time of admission and recertified that need at least every sixty days during the patient's stay in accordance with 42 U.S.C. §1396b(g)(6)(A). States which fail to make a satisfactory showing are subject to a decrease in federal financial participation ("FFP"). See State of Hawaii v. Heckler, 760 F.2d 1031 (9th Cir. 1985). Utilization control does not allow states to intrude upon utilization review. Due to their inherent conflict of interest as a payor, states are considered incapable of

performing utilization review. 42 C.F.R. §462.104(d).

The record contained uncontroverted physician affidavits which stated that many patients who would not meet the level of care criteria would be placed at serious risk by being denied admission to the hospital. By following the regulations hospital physicians would be in the position of denying admission to patients in need of services generally available only in a hospital and acting contrary to the best interests of patients. The level of care criteria at 106 CMR §§435.409 and 435.410, although adopted as a cost limitation program, could corrupt a physician's medical judgment. See Wilson v. Blue Cross of Southern California, 222 Cal. App. 3d 660, 666 (1990), citing Wickline v. State

of California, 192 Cal. App. 3d 1630, 1647 (1986), cert. granted, 231 Cal. Rptr. 560, 727 P.2d 753, review dismissed, cause remanded, 239 Cal. Rptr. 805, 741 P.2d 613 (1987) (insurance cost limitation program which subjects the treating physician's determination of medical necessity to external utilization review permits corrupt medical judgment). Cf. Hughes v. Blue Cross of Northern California, 215 Cal. App. 3d 832, 847 (1989), cert. dismissed, 495 U.S. 944 (1990) (utilization review process which relies on restrictive standard of medical necessity at variance with community standards operates in conscious disregard of insured's rights). Even the Supreme Judicial Court acknowledged: "It is no doubt true that the availability of reimbursement and the level of any

available reimbursement might indirectly affect medical judgments as to what care to provide to a patient." Jewish Memorial Hospital, 416 Mass. at 136, 617 N.E.2d at 602.

IV. THE SUPREME JUDICIAL COURT'S FAILURE TO RULE THAT MASSACHUSETTS WAS REQUIRED TO OBTAIN A WAIVER IS CONTRARY TO FEDERAL STATUTORY PROVISIONS.

The Supreme Judicial Court erred in not ruling that the Commonwealth of Massachusetts was required to obtain a waiver of federal utilization review requirements in the manner provided for by 42 U.S.C. §1396n(b). Under 42 U.S.C. §1396b(i)(4), the state may not deviate from the utilization review procedures prescribed by the Medicare program "unless the State has demonstrated to the Secretary of Health and Human Services

that it has developed a superior method and the Secretary has waived the requirements of Section 1396b(i)(4)."[5] There is nothing in the record to indicate that the Department applied for a waiver or demonstrated to HCFA that it has developed a superior method.

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[5] Examples of how the level of care regulations and preadmission screening program apply different standards and procedures and a different review committee or group than exist under the Medicare program are set forth at pp. 16-21, supra.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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Dated: December 20, 1993

APPENDIX

JEWISH MEMORIAL HOSPITAL & others[1]
vs. COMMONWEALTH
& OTHERS.[2]

Suffolk. May 6, 1993. -
August 11, 1993

PRESENT: LIACOS, C.J. WILKINS,
ABRAMS, NOLAN, & LYNCH, J.J.

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[1] Youville Rehabilitation and Chronic Disease Hospital, St. John of God Hospital, Massachusetts Respiratory Hospital, Middlesex County Hospital, New England Sinai Hospital and Rehabilitation Center, Shaughnessy-Kaplan Rehabilitation Hospital, Worcester County Hospital, and the following physicians, each of whom is associated with one of the plaintiff hospitals: Lawrence J. Kerzner, Henry H. Cho, John A. Bolzan, Mehbooba Anwar, David J. Takvoryan, Lawrence S. Hotes, and Ronald J. Pantano.

[2] The Department of Public Welfare, the Commissioner of that department, the associate commissioner of that department who is responsible for the administration of the Commonwealth's Medicaid program, and the Department of Public Health.

CIVIL ACTION commenced in the Superior Court Department on November 26, 1990.

The case was heard by Patrick J. King, J., on motions for summary judgment.

The Supreme Judicial Court on its own initiative transferred the case from the Appeals Court.

Edward D. Kalman (Rochelle H. Zapol with him) for the plaintiffs.

Judith Fabricant, Assistant Attorney General (William L. Pardee, Assistant Attorney General, with her) for the Commonwealth & others.

WILKINS, J. The plaintiff hospitals appeal from a declaratory judgment entered on May 1, 1992, in the Superior Court, following the filing of cross-motions for partial

summary judgment. That judgment upheld the lawfulness of certain regulations of the Department of Public Welfare (department) and the lawfulness of the department's 1990 request for proposals for the development of specialized facilities. We transferred the case from the Appeals Court on our own motion.

The judgment upheld 106 Code Mass. Regs. §§ 435.401 to 435.411 (1991), inclusive, against a claim that they violated the requirements of G.L. c. 6A, §32 (1992 ed.), the requirements of G.L. c. 118E, § 4 (1992 ed.), and Federal standards for Medicaid reimbursement. Those regulations are a portion of the department's regulations governing

participation in the Massachusetts Medicaid program by chronic disease, rehabilitation, and Department of Public Health hospitals and units within other facilities that perform chronic disease or rehabilitation services.[3] The plaintiffs rightly complain that the judgment fails to address their contentions that other, later numbered, sections of the department's regulations on the

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[3] The declaratory judgment only referred to 106 Code Mass. Regs. §§ 435.401-435.410 (1991). However, because of renumbering of the regulations made after argument of the case in the Superior Court but before the judgment was entered, it is clear that the judgment should have included 106 Code Mass. Regs. § 435.411 (1991) with the other regulations.

same general subject are unlawful. The complaint cited such regulations and alleged violations of law that necessarily concerned those regulations. We shall remand the case for consideration of the plaintiffs' challenges not disposed of by the declaratory judgment.

The judge rejected the plaintiffs' challenges to the department's plan to seek the development of specialized facilities to provide care for persons who have conditions that do not require hospitalization but do require services not generally available in a nursing home. In the summer of 1990, the department issued a request for proposals (RFP) for the development of such

specialized facilities. In November, 1990, the department awarded contracts to twenty bidders, three of whom are plaintiff hospitals in this case. The plaintiffs challenge the department's procedure for the creation and operation of such facilities, arguing, among other things, that the RFP violates Federal requirements for Medicaid programs and that the RFP, and the regulations together, violate rights protected by the Fourteenth Amendment to the United States Constitution.

The declaratory judgment did not dispose of the entire case, and, strictly speaking, absent a direction from the judge, the

judgment was not an appealable final judgment. See Mass. R. Civ. P. 54 (b), 365 Mass. 820 (1974). We shall, however, deal with the plaintiffs' objections to the judgment that was entered.[4]

1. The regulations. We consider first the plaintiffs'

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[4] It was within the judge's discretion to deny the plaintiffs' motion to add the Rate Setting Commission as a party and claims seeking a declaratory judgment on issues not raised in the complaint in this case.

There is also before us an appeal from the motion judge's denial in March, 1993, of the plaintiffs' motion under Mass. R. Civ. P. 60(b)(6), 365 Mass. 828 (1974), to vacate judgment based on events that occurred after the entry of the declaratory judgment. The judge did not abuse his discretion in denying that motion.

challenges to the lawfulness of certain aspects of 106 Code Mass. Regs. § 435.401 - 435.410. We address in order the plaintiffs' arguments that certain regulations violate (a) G. L. c. 6A, § 32, (b) G.L. c. 118E, § 4, and (c) Federal Medicaid reimbursement standards.

(a) The plaintiffs advance four arguments challenging regulations as violative of G.L. c. 6A, § 32. First, the plaintiffs claim that the department improperly reserved to itself in § 435.409 (A) the right to review the medical necessity of the placement of a patient in a chronic disease hospital. Section 435.409 (A) provides that "[t]he following level-of-care criteria will be used

by the Department or its agent to determine the medical necessity and appropriateness of placement in chronic disease...hospitals." It is claimed that this preadmission screening provision is contrary to a provision in § 32, added by St. 1988, c. 270, § 1, concerning rates of reimbursement for administratively necessary days. The provision in § 32 states that "[d]eterminations as to the medical necessity of patient care shall only be made by physician members of each hospital's utilization review committee, and may only be subject to review by [authorized peer review organizations]." An administratively necessary day is a day in which a Medicaid recipient

who is a hospital inpatient could properly be treated in a facility providing a lower level of care but no such facility is reasonably available. See New England Memorial Hosp. v. Rate Setting Comm'n, 394 Mass. 296, 298 (1985). The plaintiffs make no reasoned argument in support of their claim that a regulation concerning only preadmission screening (§ 435.409) is unlawful because of statutory language concerning determinations as to the medical necessity of

inpatient care. We reject this challenge to § 435.409 (A).[5]

Second, plaintiffs challenge 106 Code Mass. Regs. §§ 435.409 and 435.410, both of which concern the level of care that a patient must require to be considered an appropriate chronic disease hospital placement. The claim is that other language added to G. L. c. 6A, § 32, by St. 1988, c. 270, § 1, forbids the department from becoming involved in medical determinations in the way that it is claimed that §§ 435.409 and 435.410 allow. That language states that

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[5] Any challenge to 106 Code Mass. Regs. § 435.412 (1991) is outside the scope of the declaratory judgment.

"[d]eterminations of the medical necessity of care provided to patients by non-acute hospitals shall not be subject to any substantive standards other than generally accepted medical practice." We see no conflict. The challenged regulations concern the question whether a placement in a chronic disease hospital is appropriate for reimbursement purposes. The statutory language concerns the determination of the medical necessity for care in such a hospital. The regulation and statute relate to different subjects. It is no doubt true that the availability of reimbursement and the level of any available reimbursement might indirectly

affect medical judgments as to what care to provide to a patient. We do not, however, read the statutory language as barring the department from having control over the appropriateness for reimbursement purposes of hospital admissions for which public funds are expended. See 42 U.S.C. § 1396a (a)(30)(A) (Supp. III 1991) (department has an obligation, among other things, to "provide such methods and procedures relating to the utilization of, and the payment for, care and services...as may be necessary to safeguard against unnecessary utilization of such care and services").

A somewhat similar argument was rejected in Norfolk County Hosp. v.

Commonwealth, 25 Mass. App. Ct. 586, 592(1988), in which the court held that prior, similar regulations, defining an appropriate placement in a chronic disease hospital, did not violate the prohibition in G.L. c. 118E, § 4, against the department formulating "medical standards and criteria." Chapter 270 of the Acts of 1988 was enacted approximately six months after the Appeals Court opinion in the Norfolk County Hosp. case. If the Legislature had intended to bar the department from promulgating criteria concerning the appropriateness for reimbursement purposes of a placement in a chronic disease hospital, it should have been, and, we think, would have been, more specific.

Third, the plaintiffs argue that the department's regulations do not comply with the mandate of G.L. c. 6A, §32, that the administratively necessary day rate "shall only apply to patients for whom medically necessary care is usually provided to public assistance recipients admitted to nonhospital facilities within a twenty-five mile radius of the domicile of any individual recipient or his family." The regulations which specify when administratively necessary days are reimbursable are 106 Code Mass. Regs. §§ 435.413 and 435.414 (1991), and are beyond the scope of the declaratory judgment. The department was not obliged to deal with this subject in its

definition of administratively necessary days in § 435.402 (A).

Fourth and finally, the plaintiffs argue that the department has failed to conform its regulations to the rights of appeal established in G.L. c. 6A, § 32, as amended by St. 1988, c. 270, § 1, concerning a determination that administratively necessary day rates shall apply to a patient. The plaintiffs point to § 435.409 (B) as failing to meet the statutory standard. That section, however, provides an appeal mechanism concerning preadmission screening decisions and does not involve determinations as to administratively necessary day rates. That regulation is the only

one within the scope of the declaratory judgment that the plaintiffs challenge on the ground that it fails to provide proper appellate procedures.[6]

(b) The plaintiffs also argue that aspects of the regulations violate G.L. c. 118E, § 4, because

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[6] The plaintiffs' challenge to 106 Code Mass. Regs. § 435.417 (1991) is outside the range of the judgment, but it would fail for the same general reason, that is, the subject matter of the decision involved in § 435.417 is not one as to which G.L. c. 6A, § 32 (1992 ed.), mandates a particular appellate process.

What we say in Youville Hosp. v. Commonwealth, post (1993), concerning the hospitals' rights to declaratory relief concerning administratively necessary day rates and St. 1988, c. 270, § 1, would also justify not granting the plaintiffs relief on this fourth point.

they contain "medical standards and criteria" which § 4 states the department may not formulate.[7] This is an up-to-date reiteration of the claims made unsuccessfully by the plaintiffs in Norfolk County Hosp. v. Commonwealth, supra at 591-592, and noted earlier in this opinion. The prohibition in § 4 against the department's formulating medical standards and criteria bars the department from regulating the

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[7] Section 4 of G.L. c. 118E (1992 ed.) provides that "[i]n administering the program the department shall formulate such methods, policies, procedures, standards and criteria, except medical standards and criteria, as may be necessary for the proper and efficient operation of the plan in a manner consistent with simplicity of administration and the best interests of the recipients."

nature and degree of medical services that shall be provided to a patient. It does not, however, bar the department from determining for reimbursement purposes the medical necessity and appropriateness of a placement in a chronic disease hospital using criteria such as the adult appropriateness evaluation protocol referred to in § 435.409.

(c) The plaintiffs are wrong in asserting that 106 Code Mass. Regs. § 435.409 (A) violates Federal utilization review requirements. They have misunderstood the operation of the challenged regulation. An independent physician, not the department, has the final say on the preadmission placement decision. 106 Code Mass.

Regs. § 435.401 (B). Although a hospital must have a utilization review plan that meets Federal requirements (42 U.S.C. § 1395x[k] [1988]) in order to qualify for Medicaid reimbursement (42 U.S.C. § 1396b[i] [4] [1988]), § 435.409 (A) in no way impedes the plaintiffs from doing so. Moreover, there is no Federal prohibition against the establishment of State procedures that supplement Federal utilization review requirements. Preadmission screening, which is the subject of § 435.409(A), is a process separate from that addressed by the Federal requirements and does

not concern utilization review by its terms.[8]

2. Requests for proposals. The plaintiffs advance various objections to the department's request for proposals (RFP) for the furnishing of care to Medicaid recipients who do not need to be hospitalized in an acute care hospital, but need services not generally available in a nursing home. No contract had been negotiated at the time that summary judgment was ordered. The plaintiffs have not shown that the department's RFP is unlawful.

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[8] Challenges to § 435.412 in connection with utilization review are not before us.

The department had statutory authority to make agreements of the type contemplated with chronic disease and rehabilitative hospitals such as the plaintiffs. See G.L. c. 118E, § 4, and G.L. c. 118E, § 2(g) (1992 ed.), defining "provider." The prohibition of St. 1992, c. 133, § 2, line-item 4402-4200, against the department's selectively contracting for chronic hospital services before July 1, 1993, is not shown to be violated, was enacted after the judgment was entered in this case, and implicitly recognizes the department's authority generally to enter into such contracts.

The RFP provides that hospital reimbursement will be at negotiated rates. The Commonwealth's Medicaid

plan, then in effect, did not permit reimbursement at negotiated rates. Federal law requires that rates of reimbursement be in accordance with a Federally approved State plan. 42 C.F.R. § 447.253(i)(1992). See Quincy City Hosp. v. Rate Setting Comm'n, 406 Mass. 431, 433 (1990) (State choosing to participate in Medicaid "must submit to [Federal agency] a 'State plan' for medical assistance that comports with Federal statutory and regulatory requirements"). The defendants grant that the State plan would have to be amended in order to implement the RFP program. The judgment entered on remand should acknowledge this circumstance (adjusted, if necessary, to current

circumstances). The obligation to amend the State plan need not be satisfied before any contracts at negotiated rates are executed. See 42 C.F.R. §§ 430.20(b) and 447.256(c)(1992).

The plaintiffs' argument is premature that public notice is required before the department may contract at negotiated rates pursuant to the RFP. See 42 C.F.R. § 447.205 (1992). Moreover, it is doubtful that the plaintiffs, who already know of the circumstances, have any basis for complaint. See California Ass'n of Bioanalysts v. Rank, 577 F. Supp. 1342, 1349-1350 (C.D. Cal. 1983). The underlying issue as to whether public notice is required is whether reimbursement at

a negotiated rate is a "significant proposed change" in the department's "methods and standards for setting payment rates for services." 42 C.F.R. 447.205(a). The addition of a new method of payment seems to be a change in the method of setting payment rates for services. Whether the change is significant may depend on facts not before us, such as the impact on Medicaid expenditures. The fact that the RFP would affect only about 260 Medicaid recipients suggests that the change may not be significant in its general impact. See Missouri Dep't of Social Servs.

v. Sullivan, 957 F.2d 542, 545 (8th Cir. 1992).[9]

The plaintiffs probably have no standing to challenge the RFP program on the ground that it violates Federal law governing Medicaid patients' freedom of

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[9] The plaintiffs' complaint that there are no findings that the negotiated rates are reasonable and adequate and in accordance with law (42 U.S.C. § 1396a [a][13][A][Supp. III 1991]) is also premature. Because there were no negotiated rates, there could be no such findings.

The plaintiffs' argument that the RFP will violate Federal utilization review requirements is wrong. Nothing in the RFP exempts contract facilities from utilization review requirements that are otherwise applicable.

choice.[10] In any event, the RFP opens up a new option for such patients and in no way restricts their choices of facilities. The record does not support the claim that the RFP violates the requirement of 42 U.S.C. § 1396a(a)(10)(1988 & Supp. III 1991), and implementing regulations (42 C.F.R. §§ 440.230 and

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[10] The plaintiffs state briefly that the RFP program in certain of its aspects denies them and their patients equal protection of the laws and violates due process guarantees. The plaintiffs make no showing that classifications made by the program are constitutionally inappropriate or that they have standing to raise their patients' constitutionally-based arguments. The plaintiffs' claim that there was a dispute of material fact on the constitutional issues that barred the granting of summary judgment lacks merit.

440.240[1992]), concerning equality in the amount, duration, and scope of each service provided the categorically needy group and the covered medically needy group.

3. Although we affirm the provisions of the judgment entered, the case is remanded for consideration of such issues in the complaint that were not decided by the declaratory judgment. Circumstances may have changed so that certain issues are no longer important or are perhaps even moot. In the judge's discretion, the complaint may be amended to present current issues, but the judge may conclude that a new action based on a new record would better present any such issues. The declaratory

judgment shall be supplemented and amended to be consistent with this opinion and to resolve any undecided issues as to which there is an actual controversy.[11]

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[11] Plaintiffs' counsel could have greatly enhanced their presentation, the court's ability to deal with that presentation, and the defendants' manner of response by presenting each contention separately with supporting authority rather than grouping several points under one general topic. The issues in a case of this character are complicated by the interaction of Federal and State statutes and regulations. The facts bearing on these issues are often crucial to an understanding of them and to their resolution and should be discussed in the analysis of the issues. It is also instructive if an advocate explains why the alleged illegality of an agency regulation or any agency's course of conduct matters to the advocate's client.

Supreme Judicial Court for the
Commonwealth of Massachusetts
1412 Courthouse
Boston, Massachusetts 02108
(617) 557-1020

Edward D. Kalman, Esquire
Behar & Kalman
6 Beacon Street
Boston MA 02108

RE: No. SJC-06226

JEWISH MEMORIAL HOSPITAL & others
vs.
COMMONWEALTH & others

NOTICE OF DENIAL OF PETITION FOR REHEARING

The Petition for Rehearing filed in the above captioned case has been considered by the court and is denied.

Very truly yours,

Jean M. Kennett, Clerk

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Dated: September 23, 1993

To: Edward D. Kalman, Esquire
Rochelle H. Zapol, Esquire
Judith Fabricant, Esquire

RELEVANT STATUTES AND REGULATIONS

106 CMR 435.401

The challenged regulation codified at 106 CMR 435.401 provided as follows:

435.401: Introduction

(A) Participation 100 CMR 435.000 contains regulations governing participation in the Massachusetts Medical Assistance Program by chronic disease, rehabilitation, and Massachusetts Department of Public Health hospitals or units within other facilities performing chronic disease or rehabilitation services.

(B) Preadmission Screening. 106 CMR 435.000 describes the preadmission screening program for chronic disease and rehabilitation hospitals and applies to both in-state and out-of-state hospitals. The screening program described in this section is intended to ensure that medical and nursing services are provided in the most appropriate and cost-effective setting. The Department will pay for chronic disease ~~and~~ rehabilitation hospital services only when the Department or its agent authorizes these services based on a submission that establishes need prior to admission. (In order to expedite the process, approval may be given by telephone;

however, authorization of payment is contingent upon receipt of the completed Specialty Hospital Assessment Form.) Preadmission screening does not apply to hospital patients who were covered by other insurance (including Medicare) during part of a hospital stay and whose insurance coverage terminated prior to discharge.

(1) Hospitals with Delegated Status. Delegated hospitals shall document each recipient's need for hospitalization by completing the Department's Specialty Hospital Assessment Form and forwarding it to the Department's Long Term Care Connection (LTCC) within seven days of admission. Based on the hospital's determination, the LTCC staff will issue payment authorization forms to the recipient and to the appropriate Long Term Care Unit of the Department.

(2) Hospitals without Delegated Status.

(a) If a hospital routinely administers preadmission screenings and interviews, the hospital must complete the Specialty Hospital Assessment Form and submit it to the LTCC prior to admission.

(b) Other hospitals must notify the LTCC of impending admission. An in-person evaluation will be conducted

by an LTCC nurse to make an initial determination of the recipient's medical eligibility for admission in accordance with 106 CMR 435.000. Once a determination is made, the LTCC staff will issue payment authorization forms to the recipient and to the appropriate Long Term Care Unit.

(3) Noncoverage Determination.

In the event that the LTCC nurse's initial determination is that the recipient does not meet the level-of-care criteria of 106 CMR 435.409, the LTCC nurse shall contact the utilization-review coordinator of the hospital to determine the completeness of the medical record.

If the record is complete and no additional information is provided by the utilization-review coordinator, then the LTCC nurse shall refer the case for physician reconsideration upon the patient's request. The reconsideration will be conducted between the Department's nurse and the recipient's physician. If the Department's nurse and the recipient's physician disagree, an independent

physician in the same practice specialty as the attending physician, shall decide, utilizing the principles of medical peer review. A final determination of noncoverage will be made only by a physician.

106 CMR 435.409

The challenged regulation codified at 106 CMR 435.409 provided as follows:

> 435.409 Level-of-Care Criteria for Recipients in Chronic Disease and Massachusetts Department of Public Health Hospitals
>
> The criteria in 106 CMR 435.409 apply only to those recipients admitted to a hospital on or after the effective date of 106 CMR 435.409.

(A) Recipient Placement. The following level-of-care criteria will be used by the Department or its agent to determine the medical necessity and appropriateness of placement in chronic disease and Massachusetts Department of Public Health hospitals. Services in such hospitals are reimbursable only when available alternatives do not meet the recipient's needs, the services have been determined not to be reimbursable through Medicare or other insurance, and the recipient meets the level-of-care criteria listed in 106 CMR 435.409(A)(1). In applying these general criteria, the evaluator shall use as a guide the

Adult Appropriateness Evaluation Protocol (AEP) as used by the Peer Review Organization (PRO). The decision regarding the appropriateness of placement should not be based on the recipient's condition on the day of assessment, but must be based on the recipient's overall care plan and need for care as defined in 106 CMR 435.409(A), including the provisions listed in 435.409(A)(1) or (2).

(1) The recipient meets the following criteria:

(a) the recipient's medical condition warrants medically necessary services;

(b) the services are the type that, in light of the recipient's medical condition, can be provided safely and effectively, and cannot be provided at a lower level of care or less-costly setting (for example, a nursing facility or noninstitutional setting); and

(c) the recipient's medical condition and treatment require daily or more frequent physician supervision, or the recipient's medical condition and treatment require the constant availability of

medical services and equipment ordinarily available only in a hospital setting; or

(2) It can be shown that care in a chronic disease hospital is more cost effective, as clinical staff of the Department's medical case management program, than care in an alternative setting, and the recipient's complex medical condition prevents an alternative placement.

(B) Notice and Appeal. The notice and appeal provisions of the Department's administrative and billing regulations at 106 CMR 450.207(H) and (I) shall apply to preadmission screening decisions governed by 106 CMR 435.409.

106 CMR 435.410

The challenged regulation codified at 106 CMR 435.410 provided as follows:

435.410: Level-of-Care Criteria for Recipients Admitted to Chronic Disease Hospitals Prior to Effective Date of 106 CMR 435.409

(A) The criteria in 106 CMR 435.410 apply to those recipients admitted to a hospital prior to the effective date of 106 CMR 435.409.

(B) In order to be considered an appropriate chronic disease hospital placement, a recipient must require nursing services seven days a week for an average of 4.5 hours daily. On average, at least 1.5 hours of this nursing care must consist of skilled nursing services. Skilled nursing services include, but are not limited to, the following:

(1) nursing observation and care for a recipient's unstable or complex medical condition (for example, brittle diabetes or blood dyscrasia);

(2) administration of oral or injectable medications that require the judgment and direction of a registered nurse to monitor the dosage

and frequency and to observe the recipient for any adverse reactions to the medication. Drugs with life-threatening side effects, given as treatment for an acute condition, may require skilled nursing care. Administration of the same drug, given in a reduced dosage as a maintenance regimen, does not, in itself, indicate the need for skilled nursing care, nor does a 24-hour medication regimen;

(3) nasopharyngeal aspiration and tracheotomy care; however, long-term care of a tracheotomy tube does not, in itself, indicate the need for skilled nursing services;

(4) levin tube and gastrostomy feedings;

(5) administration of parenteral solutions on a regular and continuous basis;

(6) care of a colostomy either during an early postoperative period when related medical complications are present or when provided in combination with colostomy training. General continuous maintenance care of a colostomy can usually be performed by the patient himself or by a person without skilled training and, therefore, does not, in

itself, indicate the need for skilled nursing services;

(7) care of a suprapubic catheter or care of a urethral catheter when the insertion and maintenance of the urethral catheter is part of an active treatment for a disease of the urinary tract and irrigation is required for medical reasons (for example, when a recipient has cancer of the bladder or a resistant bladder infection).

(a) When care of a urethral catheter is the basis for recommending or approving the need for skilled nursing care, the urethral catheter must be prescribed by a physician and the need for the catheter must be documented in the recipient's medical record.

(b) The presence of a urethral catheter, particularly one placed for convenience, for the control of incontinence, or for routine irrigation, does not, in itself, indicate the need for skilled nursing care.

(c) For the purposes of 106 CMR 435.410(B)(7), a urinary tract infection caused by the use of a catheter does not

constitute a disease condition.

(8) administration of oxygen or other medical gases when they are needed on a regular and continuing basis because of the recipient's medical condition (for example, when the recipient has chronic obstructive pulmonary disease or pulmonary edema); and

(9) treatment of deep decubitus ulcers (deep area with or without necrotic tissue) or deep skin lesions when the physician has prescribed irrigation or the application of medication or sterile dressings. Infected skin lesions may require skilled nursing care to prevent the spread of the infection to other patients. When care of infected skin lesions is the basis for recommending or approving the need for skilled nursing care, the need must be documented in the recipient's medical record.

(C) In addition, the recipient must require, on average, treatment by a physician on a weekly basis. This physician intervention must be care that only a physician can provide, such as, but not limited to, the following:

(1) treatment given by the physician himself;
(2) changes in orders for treatments to be administered by the nursing staff;
(3) changes in orders for drugs to be administered by the nursing staff; and
(4) observations that can be made only by a physician.

The reason for the physician's visit, the observations made, and the proposed plan for continued treatment must be entered into the recipient's medical record. A diagnosis of terminal illness is not, in itself, sufficient reason for chronic disease hospitalization.

(D) Recipients who meet the requirements of 106 CMR 435.410(B) but do not meet the requirements of 106 CMR 435.410(C) will also be considered appropriate for chronic disease hospital placement if they are totally dependent in all activities of daily living and require at least three of the following treatments every day (or as otherwise indicated in 106 CMR 435.410(D)(1) through (10)), or if they have an assaultive or disruptive episode (here defined as one that requires controlling medication or restraint either by mechanical means or by one or more staff members) at least once weekly

and require at least three of the following treatments every day (or as otherwise indicated in 106 CMR 435.410(D)(1) through (10)):

(1) extensive dressing for deep decubiti, surgical wounds, or vascular ulcers;
(2) isolation;
(3) suctioning at least three times a week;
(4) occupational, physical, or speech/language therapy, or some combination of the three, at least five days a week;
(5) ostomy care, other than routine;
(6) oxygen;
(7) traction;
(8) wound or catheter irrigation;
(9) tube feeding; or
(10) skilled tracheostomy care

(E) The following are examples of appropriate chronic disease hospital placement:

(1) recipients who require suctioning/nasopharyngeal aspiration at least once per nursing shift or continuous use of a respirator (for example, intubation and mechanical ventilatory support);
(2) recipients with frequent life-threatening arrythmias that require monitoring and medical intervention;

(3) recipients whose severe electrolyte derangements are difficult to control;
(4) recipients with uncontrollable epileptic seizures at a frequency of more than three times weekly as documented in their medical records;
(5) recipients with multipal medical problems who are medicated with anticoagulants, chemotherapy for neoplastic diseases, or steroids that require a physician's evaluation or a drug regimen weekly;
(6) recipients receiving parenteral solutions on a frequent and continuous basis; and
(7) recipients with medical conditions that have required acute hospitalization in the past at least monthly and whose stay in a chronic disease hospital would preclude the necessity for the majority of these acute hospitalizations.

42 U.S.C. §1320c-1 provides that:

> The term "utilization and quality control peer review organization" means an entity which --
>
> (1)(A) is composed of a substantial number of the licensed doctors of medicine and osteopathy engaged in the practice of medicine or surgery in the area and who are representative of the practicing physicians in the area, designated by the Secretary under section 1320c-2 of this title, with respect to which the entity shall perform services under this part, or (B) has available to it, by arrangement or otherwise, the services of a sufficient number of licensed doctors of medicine or osteopathy engaged in the practice of medicine or surgery in such area to assure that adequate peer review of the services provided by the various medical specialties and subspecialties can be assured;
>
> (2) is able, in the judgment of the Secretary, to perform review functions required under section 1320c-3 of this title in a manner

consistent with the efficient and effective administration of this part and to perform reviews of the pattern of quality of care in an area of medical practice where actual performance is measured against objective criteria which define acceptable and adequate practice; and

(3) has at least one individual who is a representative of consumers on its governing body.

42 U.S.C. §1320c-3(a)(1)

provides that:

> Any utilization and quality control peer review organization entering into a contract with the Secretary under this part must perform the following functions:
>
> > (1) The organization shall review some or all of the professional activities in the area, subject to the terms of the contract and subject to the requirements of subsection (d) of this section, of physicians and other health care practitioners and institutional and non-institutional providers of health care services in the provision of health care services and items for which payment may be made (in whole or in part) under subchapter XVIII of this chapter (including where payment is made for such services to eligible organizations pursuant to contracts under section 1395mm of this title) for the purpose of determining whether --
> >
> > > (A) such services and items are or were reasonable and medically necessary and whether such services and items are not

allowable under subsection (a)(1) or (a)(9) of section 1395y of this title;

(B) the quality of such services meets professionally recognized standards of health care; and

(C) in case such services and items are proposed to be provided in a hospital or other health care facility on an inpatient basis, such services and items could, consistent with the provision of appropriate medical care, be effectively provided more economically on an outpatient basis or in an inpatient health care facility of a different type.

42 U.S.C. §1320c-7 provides as follows:

(a) State plan provision that functions of peer review organizations may be performed by contract with such organization

A State plan approved under subchapter XIX of this chapter may provide that the functions specified in section 1320c-3 of this title may be performed in an area by contract with a utilization and quality control peer review organization that has entered into a contract with the Secretary in accordance with the provisions of section 1395y(g) of this title.

(b) Federal share of expenditures

In the event a State enters into a contract in accordance with subsection (a) of this section, the Federal share of the expenditures made to the contracting organization for its costs in the performance of its functions under the State plan shall be 75 percent (as provided in section 1396b(a)(3)(C) of this title).

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42 U.S.C. §1395x(k) provides as follows:

(k) Utilization review

A utilization review plan of a hospital or skilled nursing facility shall be considered sufficient if it is applicable to services furnished by the institution to individuals entitled to insurance benefits under this subchapter and if it provides --

(1) for the review, on a sample or other basis, of admissions to the institution, the duration of stays therein, and the professional services (including drugs and biologicals) furnished, (A) with respect to the medical necessity of the services, and (B) for the purpose of promoting the most efficient use of available health facilities and services;

(2) for such review to be made by either (A) a staff committee of the institution composed of two or more physicians (of which at least two must be physicians described in subsection (r)(1) of this section), with or without participation of other professional personnel, or (B)

a group outside the institution which is similarly composed and (i) which is established by the local medical society and some or all of the hospitals and skilled nursing facilities in the locality, or (ii) if (and for as long as) there has not been established such a group which serves such institution, which is established in such other manner as may be approved by the Secretary;

(3) for such review, in each case of inpatient hospital services or extended care services furnished to such an individual during a continuous period of extended duration, as of such days of such period (which may differ for different classes of cases) as may be specified in regulations, with such review to be made as promptly as possible, after each day so specified, and in no event later than one week following such day; and

(4) for prompt notification to the institution, the individual, and his attending physician of any finding (made after opportunity for consultation to such attending physician) by the physician members of such committee or group that any

further stay in the institution is not medically necessary.

The review committee must be composed as provided in clause (B) of paragraph (2) rather than as provided in clause (A) of such paragraph in the case of any hospital or skilled nursing facility where, because of the small size of the institution, or (in the case of a skilled nursing facility) because of lack of an organized medical staff, or for such other reason or reasons as may be included in regulations, it is impracticable for the institution to have a properly functioning staff committee for the purposes of this subsection. If the Secretary determines that the utilization review procedures established pursuant to subchapter XIX of this chapter are superior in their effectiveness to the procedures required under this section, he may, to the extent that he deems it appropriate, require for purposes of this subchapter that the procedures established pursuant to subchapter XIX of this chapter be utilized instead of the procedures required by this section.

42 U.S.C. §1396a(a)(30)(A)

provides, in relevant part, that the state Medicaid agency must:

> provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan (including but not limited to utilization review plans as provided for in section 1396b(i)(4) of this title) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care;...

42 U.S.C. §1396b(g)(6)(A)

provides that:

(6)(A) Recertifications required under section 1902(a)(44) shall be conducted at least every 60 days in the case of inpatient hospital services.

42 U.S.C. §1396b(i)(4)

provides, in relevant part, that:

(4) with respect to any amount expended for care or services furnished under the plan by a hospital unless such hospital has in effect a utilization review plan which meets the requirements imposed by section 1395x(k) of this title for purposes of subchapter XVIII of this chapter; and if such hospital has in effect such a utilization review plan for purposes of subchapter XVIII of this chapter, such plan shall serve as the plan required by this subsection (with the same standards and procedures and the same review committee or group) as a condition of payment under this subchapter; the Secretary is authorized to waive the requirements of this paragraph if the State agency demonstrates to his satisfaction that it has in operation utilization review procedures which are superior in their effectiveness to the procedures required under section 1395x(k) of this title;...

42 U.S.C. §1396n(b) provides as follows:

(b) Waivers to promote cost-effectiveness and efficiency

The Secretary, to the extent he finds it to be cost-effective and efficient and not inconsistent with the purposes of this subchapter, may waive such requirements of section 1396a of this title as may be necessary for a State--

(1) to implement a primary care case-management system or a specialty physician services arrangement which restricts the provider from (or through) whom an individual (eligible for medical assistance under this subchapter) can obtain medical care services (other than in emergency circumstances), if such restriction does not substantially impair access to such services of adequate quality where medically necessary,

(2) to allow a locality to act as a central broker in assisting individuals (eligible for medical assistance under this subchapter) in selecting among competing health care plans, if such restriction does not substantially impair access

to services of adequate quality where medically necessary,

(3) to share (through provision of additional services) with recipients of medical assistance under the State plan cost savings resulting from use by the recipient of more cost-effective medical care, and

(4) to restrict the provider from (or through) whom an individual (eligible for medical assistance under this subchapter) can obtain services (other than in emergency circumstances) to providers or practitioners who undertake to provide such services and who meet, accept, and comply with the reimbursement, quality, and utilization standards under the State plan, which standards are consistent with access, quality, and efficient and economic provision of covered care and services, if such restriction does not discriminate among classes of providers on grounds unrelated to their demonstrated effectiveness and efficiency in providing those services.

No waiver under this subsection may restrict the choice of the

individual in receiving services under section 1396d(a)(4)(C) of this title.

42 C.F.R. §462.104(d) provides that:

> (d) A State government that operates a Medicaid program will be considered incapable of performing utilization and quality review functions in an effective manner, unless the State demonstrates to the satisfaction of HCFA that it will act with complete independence and objectivity.

42 C.F.R. §482.30(c) provides that:

> The hospital must have in effect a utilization review (UR) plan that provides for review of services furnished by the institution and by members of the medical staff to patients entitled to benefits under the Medicare and Medicaid programs.
>
> ...
>
> (c) Standard: Scope and frequency of review. (1) The UR plan must provide for review for Medicare and Medicaid patients with respect to the medical necessity of--
>
> (i) Admissions to the institution;
>
> (ii) The duration of stays; and
>
> (iii) Professional services furnished, including drugs and biologicals.
>
> (2) Review of admissions may be performed before, at, or after hospital admission.

(2)

Supreme Court, U.S.
FILED
JAN 19 1994
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No. 93-1045

IN THE
SUPREME COURT OF THE UNITED STATES
October Term, 1993

JEWISH MEMORIAL HOSPITAL, et al.
Petitioners,
v.
COMMONWEALTH OF MASSACHUSETTS, et al.
Respondents.

On Petition for Writ of Certorari
to the Supreme Judicial Court
of Massachusetts

RESPONDENTS' BRIEF IN OPPOSITION

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ISSUES PRESENTED

Whether federally-approved Massachusetts regulations requiring utilization control procedures for Medicaid-funded services in chronic hositals are consistent with utilization review requirements prescribed by Title XIX of the Social Security Act.

PARTIES TO THE PROCEEDNGS

The parties to the proceedings are accurately listed in the petition for certiorari at pp. 1-3.

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No. 93-1045

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October Term, 1993

JEWISH MEMORIAL HOSPITAL, et al.

Petitioners,

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Respondents.

On Petition for Writ of Certiorari
to the Supreme Judicial Court
of Massachusetts

RESPONDENTS' BRIEF IN OPPOSITION

Pursuant to Supreme Court Rule 15, Respondents submit this brief in opposition to the petition for writ of certiorari ("Pet.").

DECISIONS BELOW

The opinion of the Supreme Judicial Court for the Commonwealth of Massachusetts ("SJC") is reported at 416 Mass. 132, 617 N.E.2d 598 (1993), and is reproduced at pp. A1-A29 of the appendix to the petition ("Pet. App."). The SJC's rescript is reproduced at p. A1 of the appendix to this brief in opposition ("Opp. App."). The decision of the Superior Court is not reported.

JURISDICTION

The opinion and order of the Supreme Judicial Court were entered on August 11, 1993. The SJC denied a Petition for Rehearing on September 23, 1993. The petition was filed on December 21, 1993, and was received by Respondents on the same day. The petitioners invoke the

Court's jurisdiction pursuant to 28 U.S.C. § 1257(a). Respondents contend that this Court lacks jurisdiction because the decision of the SJC is not a final judgment.

RELEVANT STATUTORY AND REGULATORY PROVISIONS

The text of the relevant statutory and regulatory provisions is accurately set forth in the appendix to the petition, Pet. App. A32-A61, with two minor exeptions not material to the issues on which review is sought.1/

1/ The two errors are as follows:
At Pet. App. 55, "1902(a)(44)" should read "1396a(a)(44)."
At Pet. App. 32, part (A), "100 C.M.R. 435.000" should read "106 C.M.R. 435.000."

STATEMENT OF THE CASE

An accurate statement of the case appears in the opinion of the Supreme Judicial Court of Massachusetts, at Pet. App. A2-A7. However, the opinion does not fully describe the challenged regulations, and the petition mischaracterizes the regulations.[2/]

The challenged regulations concern operation of the Massachusetts Medicaid

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[2/] The petition repeatedly asserts contentions regarding the effects of the regulations on decisions regarding patient care and placement, relying for these assertions on what it describes as uncontroverted physician affidavits contained in the state court record. The affidavits relied on merely assert the plaintiff physicians' misinterpretation of the challenged regulations, not factual matters within the affiants' personal knowledge. Accordingly, the state courts properly gave them no weight.

program, pursuant to Title XIX of the Social Security Act and the Commonwealth's Medicaid Plan, which has been approved by the Secretary of Health and Human Services. As will be explained more fully infra, the specific regulations in issue here have also received approval from the Secretary through the Health Care Financing Administration ("HCFA").

The challenged regulations have two principal effects: First, they require compliance with a pre-admission screening procedure as a condition of Medicaid reimbursement for chronic hospital services. Second, they establish new level-of-care criteria for determination of the appropriateness of chronic hospital placement.

Pre-admission screening is a process by which reimbursement for in-patient services is conditioned on advance approval of the admission by the entity providing reimbursement, or by some screening agency acting for it. Over the past decade, pre-admission screening has become routine among non-governmental third party payers, such as insurance carriers and health maintenance organizations. Feldstein, P., et al., Private Cost-Containment: The Effects of Utilization Review Programs on Health Care Use and Expenditures, 318 New Eng. J. Med. 1310,

1311 (1988).[3]

The Massachusetts Medicaid program implemented a pre-admission screening requirement for acute-care hospitals in February of 1988, see 106 C.M.R. § 450.207 (Rev. 8/1/90). The program has also required pre-admission screening for child psychiatric hospitals since approximately 1985 (R.A. 519-523).[4]

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[3] HCFA began to institute a pre-admission screening program for both Medicare and Medicaid in 1975; implementation of that program was barred temporarily by a preliminary injunction, but that injunction was vacated and the case dismissed upon HCFA's agreement to make certain changes in the requirements of the program. American Medical Association v. Weinberger, 522 F.2d 921 (7th Cir. 1975); see 42 C.F.R. Ch. IV (10-1-89 Edition), at 250-1 & n.1.

[4] References to the record appendix filed with the SJC are denoted herein as "R.A. __".

Similar prior approval requirements have applied to nursing home placements since at least 1981. See Mass. St. 1981, c. 351, § 186. Indeed, until the challenged regulations took effect on March 1, 1991, chronic and rehabilitation hospitals were the only type of institutional provider of Medicaid services in Massachusetts that were not subject to pre-admission screening. The regulations in issue here extended this requirement, already in place for others, to this one remaining category of institutional provider.5/

5/ Specified outpatient services have also required advance approval since as early as 1969. Mass. Gen. L. c. 118E, § 7, enacted by Mass. St. 1969, c. 800, § 1.

The regulations describe the process for obtaining pre-admission approval. Hospitals which meet specified requirements for "Delegated Status" are authorized to conduct the screening themselves; in these instances, Medicaid staff are required to authorize payment based solely on the hospital's own determination. 106 C.M.R. § 435.401(B)(1). Other hospitals are required to notify the Medicaid agency[6/] of the impending admission. 106 C.M.R. § 435.401(B)(2). A Department staff nurse then makes an initial determination of whether the patient meets the applicable level-of-care criteria; if so the nurse

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6/Formerly the Department of Public Welfare, now the Division of Medical Assistance.

authorizes payment. 106 C.M.R. § 435.401(B)(2)(b).

If the initial determination is negative, the nurse is required to contact the hospital for any additional information available. 106 C.M.R. § 435.401(B)(3). If the determination remains negative at this point, the nurse "shall refer the case for physician reconsideration upon the patient's request." 106 C.M.R. § 435.401(B)(3). That reconsideration is to be conducted "between the Department's nurse and the recipient's physician" (emphasis added). 106 C.M.R. § 435.401(B)(3). If the two still disagree, "an independent physician, in the same practice specialty as the attending physician, shall decide, utilizing the principles of medical peer

review." 106 C.M.R. § 435.401(B)(3); A19 (SJC opinion). In case any conceivable doubt remains, the regulation goes on to state that, "[a] final determination of non-coverage will be made only by a physician." Such negative determinations, moreover, trigger procedures for notice and administrative appeal. 106 C.M.R. § 435.409(B).

The level-of-care criteria established at 106 C.M.R. § 435.409 serve as the substantive standards governing pre-admission screening. That is, these criteria describe the circumstances under which a patient is considered to need care at a hospital level, as opposed to out-patient or in a nursing home or other facility.

Massachusetts Medicaid regulations have established level-of-care criteria for hospital services since 1977 (R.A. 518). See Norfolk County Hospital v. Commmonwealth, 25 Mass. App. Ct. 586, 591, 521 N.E.2d 406, 409 (1988) (upholding earlier level-of-care criteria for chronic hospitals); Pet. App. 14 (SJC opinion). With respect to these criteria, the regulatory amendments in issue here do not establish a new program, or abolish any existing program. These amendments do, however, make certain changes in the criteria themselves, primarily to bring them into closer conformity with criteria applicable under the Medicare program.

Under the Medicare statute, 42 U.S.C. § 1395x(k) (1988), all in-patient

hospital services are subject to utilization review for medical necessity by a Peer Review Organization. See also 42 C.F.R. §§ 412.44, 466.70-71 (1990). As the Petitioners themselves admitted in affidavits submitted to the Superior Court, the Peer Review Organizations base those determinations on application of the Adult Appropriateness Evaluation Protocol ("AEP") (R.A. 15, 93, 99, 108, 119, 129, 139, 142, 180).

The AEP is an "objective criteria-based system for the determination of appropriateness of hospital days of care." Gertman, P., and Restuccia, J.; The Appropriateness Evaluation Protocol: A Technique for Assessing Unnecessary Days of Hospital Care, XIX Med. Care 855, 857 (August

1981). The AEP consists of a set of criteria in three categories: medical services, nursing/life support services, and patient condition factors. Id. at 857. Under the AEP, a patient who meets any of the criteria is considered to be appropriately hospitalized. Id. In addition to the specified objective criteria, the AEP includes "a system of 'overrides,'" which allow a determination, based on individualized physician judgment, that hospitalization is appropriate despite the absence of any listed criteria. Id. at 858. The AEP was "developed by Boston University researchers working in consultation with physicians in Massachusetts professional standards review organizations." Siu, A., et al., Inappropriate Use of

Hospitals in a Randomized Trial of Health Insurance Plans, 315 New Eng. J. Med. 1259, 1260 (1986). The AEP has been repeatedly tested and validated in published professional studies, and has been found to be "a valid and reliable instrument." Id. at 1260, and sources cited.7/

The criteria set forth in the regulations do not, however, require determinations based on a mechanical application of the AEP. Rather, 106 C.M.R. § 435.409(A) provides that the AEP is to be used "as a guide" in the

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7/ Because of the system of overrides, the fact that development and testing of the AEP has focused on acute hospitals does not make its use for chronic hospital admissions inappropriate. Rather, this fact means only that physician review will be required more frequently than might be the case if a more specifically targeted protocol were used.

determination of whether the patient meets the criteria specified at §§ 435.409(1) and (2). Moreover, since the AEP itself provides for flexibility, that very flexibility is incorporated in its use under the regulations. Thus, to the extent that the AEP itself authorizes overriding of its specific criteria based on physician judgment with respect to a particular patient's circumstances, the regulation incorporates that authorization.

The regulatory criteria themselves, 106 C.M.R. §§ 435.409(1) and (2), are broad and flexible. In essence, the test is whether the patient needs services of a type that "in light of the recipient's medical condition," cannot be provided in a lower level setting.

106 C.M.R. § 435.409(A)(1)(b). In addition, the patient must be in need of either "daily or more frequent physician supervision," or "constant availability of medical services and equipment ordinarily available only in a hospital setting." 106 C.M.R. § 435.409(A)(1)(c). Thus, a patient whose condition is so unstable as to pose a risk of rapid deterioration would qualify based on a need for constant availability of physician response, even without an ongoing need for daily physician supervision. Finally, 106 C.M.R. § 435.409(A)(2) provides a catch-all alternative, authorizing admission, even absent the other criteria, when chronic hospital placement "is more cost-effective" than

alternatives, and "the recipient's complex medical condition prevents an alternative placement."

The regulations do not purport to govern determinations of the medical necessity of any treatment or procedure provided to any patient. Such determinations are left entirely to physicians. Rather, the regulations merely ensure that whatever treatment physician judgment determines to be necessary is delivered in the most cost-effective setting. Pet. App. 12-13 (SJC opinion).

Under regulations that pre-date these changes, the level-of-care criteria serve a second function, in addition to their role as substantive standards for pre-admission screening.

Under 106 C.M.R. § 435.412, each hospital is required to engage in a continuous process of utilization review ("UR"), applying the level-of-care criteria. UR, which federal law also requires, is the examination of utilization records, by the hospital's own medical staff or by the Peer Review Organization ("PRO"), to determine the appropriateness and medical necessity of hospital services being provided or already provided. See, e.g., 42 U.S.C. § 1395x(k)(3) (review "to be made as promptly as possible, after each day so specified [in regulations], and in no event later than one week following such day"). Among other consequences, UR can result in determinations that some part of a patient's hospital stay is

reimbursable not at the hospital's regular rate, but at a lower rate designated for "Administratively Necessary Days" ("AND's"). 106 C.M.R. § 435.413 and 414.[8/] Nothing in these amendments changes the UR process, or its implications for reimbursement at AND rates, or the fact that UR is conducted by the hospitals' own staff or the PRO, in accord with the level-of-care criteria set in these regulations. Pet. App. 20 (SJC opinion).

During the course of its consideration of the regulations now under challenge, the Massachusetts

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[8/] For reasons specific to state law and not relevant here, the application of AND rates does not actually decrease Medicaid reimbursement to chronic hospitals in Massachusetts. See Youville Hospital v. Commonwealth, 416 Mass. 142, 145, 617 N.E.2d 605, 607 (1993).

Department of Public Welfare engaged in a series of correspondence with HCFA regarding the relationship between the regulations and applicable federal law. Petitioners also participated in this process, expressing their objections to the regulations, including the arguments presented in the petition, in a series of letters from their counsel to HCFA. In a letter dated December 21, 1990, HCFA's Associate Regional Administrator expressed approval of the regulations, indicating that nothing in them supplied a basis for any compliance action against the Commonwealth (R.A. 543). The letter went on to comment that:

> We want to reiterate that the State Medicaid agency may place appropriate limits on coverage of services based on such criteria as medical necessity and utilization control

> procedures, and that the State Medicaid agency should not cover services that it considers to be medically unnecessary, or medically unnecessary in a particular setting. The State Medicaid agency has some latitude in this regard, and we show appropriate deference to the State agency's judgments in these matters insofar as they are not contrary to the specific requirements of Title XIX.

(R.A. 543).

REASONS FOR DENYING THE WRIT

"A review on writ of certiorari is not a matter of right but of judicial discretion." Sup. Ct. R. 10.1. Such a writ is granted "only when there are special and important reasons therefor." Id. The purpose of certiorari jurisdiction is to permit the Court to select cases of "such gravity and general importance" as to warrant

plenary review. In re Woods, 143 U.S. 202, 206 (1892).

For the reasons set forth below, the petition does not satisfy the traditional criteria which guide the Court's discretionary review. Accordingly, the petition should be denied.

I. THIS COURT LACKS JURISDICTION BECAUSE THE DECISION OF THE SUPREME JUDICIAL COURT IS NOT A FINAL JUDGMENT.

The order of the Supreme Judicial Court directed that the case be "remanded for consideration of such issues in the complaint that were not decided by the declaratory judgment," and that "the declaratory judgment shall be supplemented and amended to be consistent with this opinion and to resolve any undecided issues as to which

there is an actual controversy" (A1). Thus, the SJC's decision has not ended the case, but only moved it to its next stage, which will occur in the Massachusetts Superior Court, subject thereafter to appellate review once again.

Even with respect to the particular issues decided by the SJC, including the federal issue presented in the petition, the judgment to be entered is not yet established, since the SJC has directed that the declaratory judgment be amended. Moreover, as the SJC explained in its opinion, because the judgment it reviewed did not dispose of the entire case, it was not final and thus technically not appealable; the SJC considered the issues raised pursuant to

its discretionary authority under state law. Pet. App. 6-7 (SJC opinion). Thus, the SJC's decision is not a "final judgment" subject to review in this Court under 28 U.S.C. § 1257. See Collins v. Miller, 252 U.S. 364, 370 (1920).

II. THE PETITION PRESENTS NO GROUND FOR REVIEW UNDER THE CRITERIA SET FORTH IN RULE 10 OF THIS COURT'S RULES.

The Petition does not even purport to set forth a basis for review under Rule 10 of this Court's rules. It does not contend that the SJC has decided a federal question in conflict with another state's highest court or with a United States Court of Appeals, nor does it contend that the SJC has decided an important question of federal law that should be settled by this Court, or has

decided such a question in conflict with a decision of this Court. Rather, petitioners' contention, in essence, is nothing more than that the SJC decision is wrong. That claim presents no special or important reason for review. Sup. Ct. R. 10; See Hamilton Shoe Co. v. Wolf Bros., 240 U.S. 251, 258 (1916); In re Woods, 143 U.S. at 206.

Indeed, the Petition cites no decisions of this or any federal court, or of any state court, addressing the federal question it purports to raise: whether the particular federal statutory provisions on which petitioners rely bar a state Medicaid agency from conditioning hospital reimbursement on compliance with regulations mandating pre-admission screening and setting

level-of-care criteria. That question can hardly be considered of such inherent importance as to warrant resolution by this Court in the absence of any indication of conflict among lower courts.

The closest the petition comes to invoking the criteria of Rule 10 is its assertion that the SJC decision conflicts with Blum v. Yaretsky, 457 U.S. 991 (1982) (Pet. 27). That assertion rests on a misreading of both decisions.

This Court's holding in Blum v. Yaretsky addressed the issue of whether a nursing home's implementation of state utilization control regulations was state action subject to the fourteenth Amendment. 457 U.S. at 993, 1002-3,

1005, 1012. Blum did not purport to construe the Social Security Act, still less the particular provisions on which petitioners here rely; its references to the operation of provisions of that statute were by way of background to present the context in which the state action question arose.

Furthermore, the claimed inconsistency evaporates on reading of the SJC's decision, which, in contrast to the petition's distorted paraphrase, in no way departs from Blum's description of the Medicaid program. The petition, at p. 27, quotes part of a sentence from the SJC's opinion, misstates the remainder of the passage, and thus presents a purported distinction that the SJC never made. The SJC's actual language was as follows:

> The challenged regulations concern the question whether a placement in a chronic disease hospital is appropriate for reimbursement purposes. The statutory language concerns the determination of the medical necessity for care in such a hospital.

(Pet. App. 12)

The SJC's distinction was not, as petitioners' contend, between placement for medical necessity purposes, and placement for reimbursement purposes; the distinction, rather, was between placement and "care" -- i.e., between the decision as to the facility in which services are rendered, and the decision as to what services are to be rendered to a patient. Thus the SJC's decision in no way conflicts with Blum's recitation of the requirement that medically necessary services, and only

those services, be reimbursed under Medicaid.

Moreover, the SJC's discussion in which this language appears did not relate to the federal question on which petitioners seek this Court's review. Rather, the quoted language related to a wholly state law issue petitioners had presented to the state courts: that is, whether the regulations were inconsistent with a state statute, Mass. St. 1988, c. 270, § 1, regarding the process by which "determinations of the medical necessity of care" are to be made. Thus, the SJC construed the word "care," as used in that statute, and distinguished it from placement, which the challenged regulations address. The SJC's ruling on this state law question

has no bearing on the federal issue presented for review, and in no way conflicts with Blum.

III. THE SJC CORRECTLY HELD THE REGULATIONS, WHICH HCFA HAS APPROVED, CONSISTENT WITH THE SOCIAL SECURITY ACT

Under both federal and state law, Medicaid reimbursement is limited to services that are "medically necessary," and that are rendered in an appropriate setting. 42 U.S.C. § 1396a(a)(30)(A)(1988); 42 C.F.R. § 440.230(d)(1990); Mass. Gen. L. c. 118E, § 6; 106 C.M.R. § 450.204; See Blum v. Yaretsky, 457 U.S. at 994. If the care needed by a particular patient can be provided in a non-hospital setting, then hospitalization of that patient is not reimbursable. See 42 C.F.R. § 466.86(a)(3).

This limitation is of particular fiscal significance; Congress has recognized the extremely high cost of inpatient hospital services, as compared with care in nursing homes and other less intensive settings. S. Rep. No. 404, 89th Cong., 1st Sess. (1965), reprinted in 1965 U.S.C.C.A.N. 1943, 1987 (patients should remain in hospitals only as long as necessary, moving to other facilities that "provide less expensive, but equal, care").

Federal law requires the state Medicaid agency to ensure compliance with the requirements of both medical necessity of services and appropriateness of setting. E.g., 42 U.S.C. § 1396a(a)(30)(A); 42 C.F.R. § 456.1. The federal scheme requires

the state to "safeguard against unnecessary utilization of such care and services," through the use of methods "including but not limited to utilization control plans." 42 U.S.C. § 1396a(a)(30)(A). Under federal law, if HCFA were to determine that the Commonwealth had failed to meet the requirement of limiting reimbursement to medically necessary services, it could deny federal reimbursement for those expenditures. 42 U.S.C. § 1396b(a)(1) (1988).

Petitioners rely on 42 U.S.C. § 1396b(i)(4), which prohibits federal reimbursement for payments to any facility "unless such hospital or skilled nursing facility has in effect a utilization review plan which meets the

requirements imposed by § 1395x(k) of this title." On its face, this provision limits Medicaid reimbursement to hospitals that conform to the utilization review ("UR") requirements of the Medicare program. As the SJC held, Pet. App. 20, the statute does not prohibit states from imposing any additional requirements that are compatible with Medicare UR standards. Most importantly, the statute says nothing whatever about pre-admission screening.

The Medicare standards referred to appear at 42 U.S.C. § 1395x(k). That statute provides that a hospital UR plan "shall be considered sufficient" if it meets the specified requirements. Nothing in § 1395x(k) limits hospitals

from adopting additional UR or other utilization control procedures, nor does the statute in any way prohibit states from conditioning reimbursement on hospitals' compliance with additional procedures. The regulations challenged here in no way impede hospitals' compliance with the federal requirement. Rather, the regulations merely add the additional, fully compatible step of pre-admission screening to the overall utilization control system.

Any doubt that may remain as to the consistency between the regulations and federal law should be resolved on the basis of HCFA's determination that the two are fully consistent (R.A. 543-44). The Court should give weight to this

interpretation of the federal scheme by the agency charged with enforcing it. Miller v. Youakim, 440 U.S. 125, 144 (1979); Rosado v. Wyman, 397 U.S. 397, 406-407 (1970).

CONCLUSION

For the foregoing reasons, this Court should deny the petition.

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Dated: January 20, 1994

WPPJF2/381

COMMONWEALTH OF MASSACHUSETTS

Supreme Judicial Court
for the Commonwealth

At Boston

August 11, 1993

IN THE CASE No. SJC 6226

JEWISH MEMORIAL HOSPITAL & others

v.

COMMONWEALTH & others.

pending in the Superior Court Department of the Trial Court for the County of Suffolk No. 90-7114

The case is remanded for consideration of such issues in the complaint that were not decided by the declaratory judgment. In the judge's discretion, the complaint may be amended to present current issues. The declaratory judgment shall be supplemented and amended to be consistent with this opinion and to resolve any undecided issues as to which there is an actual controversy.

By the Court,

s/Susan Mellen, Ass't Clerk

August 11, 1993

See opinion on file.

Supreme Court, U.S.
FILED
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NO. 93-1045

IN THE SUPREME COURT OF THE
UNITED STATES

OCTOBER TERM, 1993

JEWISH MEMORIAL HOSPITAL, ET AL.,

Petitioners,

v.

COMMONWEALTH OF MASSACHUSETTS,
ET AL.,

Respondents.

On Petition For Writ of Certiorari
To The Supreme Judicial Court
Of Massachusetts

PETITIONERS' REPLY BRIEF TO RESPONDENTS' BRIEF IN OPPOSITION

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NO. 93-1045

IN THE SUPREME COURT OF THE
UNITED STATES

OCTOBER TERM, 1993

JEWISH MEMORIAL HOSPITAL, ET AL.,

Petitioners,

v.

COMMONWEALTH OF MASSACHUSETTS,
ET AL.,

Respondents.

On Petition For Writ of Certiorari
To The Supreme Judicial Court
Of Massachusetts

PETITIONERS' REPLY BRIEF TO RESPONDENTS' BRIEF IN OPPOSITION

Pursuant to Supreme Court Rule 15.6, the Petitioners submit this reply brief in response to the "Respondents' Brief in Opposition."

REASONS FOR GRANTING THE PETITION

I. THIS COURT HAS JURISDICTION UNDER 28 U.S.C. §1257(a) BECAUSE THE DECISION OF THE SUPREME JUDICIAL COURT IS FINAL AS TO THE FEDERAL ISSUE RAISED.

Review is being sought of the following provision of the declaratory judgment which was affirmed by the Supreme Judicial Court: "The Department of Public Welfare's regulations set forth in 106 C.M.R. §§435.401-410 as amended effective March 1, 1991... do not violate the requirements of 42 U.S.C. §1396b(i)(4),..." R.A. 351.[1] The Respondents point to no other federal issues related to preadmission review that are to be considered by the Superior Court on remand.

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[1] References to the record appendix filed with the Supreme Judicial Court are denoted as "R.A. __".

In Cox Broadcasting Corp. v. Cohn, 420 U.S. 469 (1975), this Court noted four situations in which the adjudication of a federal issue in a case by the highest available state court was reviewable in this Court even though further state court proceedings were to take place. This case falls within two of the exceptions. The issue of federal law has been decided by the Supreme Judicial Court. Any additional proceedings in State Superior Court would not require a decision on other federal questions concerning preadmission review that might require review at a later date. Cox Broadcasting Corp., 420 U.S. at 480, citing Radio Station WOW v. Johnson, 326 U.S. 120, 127 (1945).

To the extent that any amendment to the judgment could affect the

federal issue presented in the Petition for Writ of Certiorari ("the Petition"), the Respondents have not suggested that the Supreme Judicial Court's affirmance of the State Superior Court's declaration that the regulations set forth in 106 C.M.R. §§435.401-410 do not violate the requirements of 42 U.S.C. §1396b(i)(4), makes the outcome of any amendment on this issue anything but preordained.[2] Cox Broadcasting Corp., supra, at 479. For purposes of this Court's jurisdiction, the

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[2] For example, the Supreme Judicial Court noted that the lawfulness of other, later numbered sections of the Department's regulations on the same general subject is not addressed in the judgment. Jewish Memorial Hospital, 416 Mass. 132, 134, 617 N.E.2d 598, 600 (1993).

decision of the Supreme Judicial Court is final as to the federal issue raised.

II. THE PETITION PRESENTS AN IMPORTANT FEDERAL ISSUE.

The issue is whether Massachusetts' preadmission screening and level of care regulations conflict with federal utilization review requirements prescribed by 42 U.S.C. §1396b(i)(4). Congress directed that utilization review for Medicaid patients (which includes preadmission review) be conducted using the same procedures and standards used for Medicare patients. 42 U.S.C. §1396b(i)(4). By establishing different procedures and standards than those required by the Social Security Act, the Massachusetts preadmission review

program and level of care criteria conflict with this Congressional mandate.[3]

Resolution of the federal question is important because at present Petitioner hospitals and physicians are placed in an untenable position when a hospital's utilization review committee concludes that hospitalization of a Medicaid patient is medically necessary but Massachusetts preadmission review standards dictate

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[3] The fact that the Massachusetts requirements are different from the Medicare requirements is confirmed by the Respondents. The Respondents state that certain amendments were made to bring Massachusetts requirements "intc closer conformity with criteria applicable under the Medicare program". Brief at 12. Thus, it is undisputed that Massachusetts criteria are not the same as the Medicare criteria.

that hospitalization is not "appropriate for reimbursement purposes". Jewish Memorial Hospital, 416 Mass. at 136, 617 N.E.2d at 602. The Petitioners must either admit the patient and not be reimbursed for care determined to be medically necessary at a hospital level by the utilization review committee or refuse to admit the patient and be exposed to malpractice claims.

The distinction drawn by the Massachusetts Supreme Judicial Court and by the Respondents between care which is "medically necessary" and care for which reimbursement is appropriate is not permitted under federal law. Medical care which is medically necessary and included in the state plan must be covered.

In their opposition, Respondents now claim that the distinction is

between "placement" and "care". Brief at 29. Placement and care cannot be neatly compartmentalized as suggested by the Respondents. The type of care a patient receives is dictated by the facility in which the patient is placed. It is axiomatic that the same level of care and medical resources are not available in a hospital and a nursing home.

As a result of the conflict between the federal requirements and the Massachusetts regulations, Medicaid recipients are placed in a Catch-22 dilemma. Care may be determined medically necessary under federal utilization review standards but Massachusetts may still conclude that placement is not reimbursable under state standards. Congress sought to avoid just such a dilemma by directing that utilization review

be conducted using the same standards for Medicare and Medicaid.

The conflict between the federal statutory and regulatory requirements and the Massachusetts regulations implicates important concerns and warrants granting certiorari.[4] See Kolovrat v. Oregon, 366 U.S. 187, 191 (1961) (certiorari granted where state statute conflicted with federal statute notwithstanding no conflict of the circuits, and no conflict with another state's highest court). In Kolovrat, as here there was simply a claim that the state court was wrong.

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[4] Respondents' reliance on In Re Woods, 143 U.S. 202, 206 (1892) is misplaced. The questions presented in that case involved solely state law and common law. Certiorari had been sought in order to "avert diversity of judgments..." Id.

This Court required that the state policy "give way" to the federal policy. Id. at 190. Similarly, in this case, the Massachusetts regulations conflict with federal law and must give way to the federal requirements.[5]

III. THE SUPREME JUDICIAL COURT ERRED IN HOLDING THAT THE REGULATIONS ARE CONSISTENT WITH THE SOCIAL SECURITY ACT.

A. The Health Care Financing Administration Has Not Made A Determination That the Regulations Are Consistent With Federal Law.

The Respondents argue that the Health Care Financing Administration (HCFA) has made a determination that the regulations are consistent with federal law. A December 21, 1990 letter from HCFA's Associate Regional

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[5] The phrase "a statute of any state" in 28 U.S.C. §1257 includes a regulation. See Lathrop v. Donohue, 367 U.S. 820, 825 (1961).

Administrator relied upon by the Respondents is not an official ruling, interpretation or advisory opinion issued by the Administrator of HCFA. Even if it were, an interpretive ruling by HCFA is not controlling on the courts. Daughters of Miriam Center for the Aged v. Mathews, 590 F.2d 1250, 1263 (3d Cir. 1978). The letter does not represent a federal finding that the regulations conform to federal law. Rather, the letter merely represents HCFA's acceptance of the Respondents' assurances on this issue. Under the Medicaid program, federal officials routinely accept assurances provided by state officials. For example, in the context of reimbursement, they do not require a State to submit findings or underlying data to determine the truth or validity of

those assurances. Wilder v. Virginia Hospital Ass'n, 496 U.S. 498, 508 (1990).

Under the Medicaid program, the State may not deviate from the utilization review standards and procedures prescribed by the Medicare program unless the State demonstrates to the Secretary of Health and Human Services that it has developed utilization review procedures which are superior in their effectiveness and the Secretary waives the requirements of §1396b(i)(4). 42 U.S.C. §1396b(i)(4). The record indicates that the State did not obtain a waiver of federal utilization review requirements in the manner provided for by 42 U.S.C. §1396n(b) or demonstrate to HCFA that it has developed a superior method. The State admitted as much in its

answer to the complaint. R.A. 156. The HCFA letter cited by the Respondents does not state that preadmission review is not part of utilization review and does not address the Respondents' failure to obtain a waiver as required by federal law.

Accordingly, the Court should look behind the assurances provided by the State to determine whether the regulations are consistent with federal law, specifically, 42 U.S.C. §1396b(i)(4).

B. <u>There is No Federal Regulation Prescribing Preadmission Screening Review Requirements For Medicare and Medicaid</u>.

The Respondents refer to Massachusetts Medicaid preadmission screening programs for acute care hospitals and child psychiatric

hospitals in an effort to lend validity to the preadmission screening program for chronic disease and rehabilitation hospitals. Brief, p. 7. The validity of these other programs was not raised by the Respondents and cannot transform the illegal preadmission regulations at issue here into regulations that comply with federal law.

The Respondents also refer to a preadmission screening program for Medicare and Medicaid which HCFA began to institute in 1975, citing American Medical Association v. Weinberger, 522 F.2d 921 (7th Cir. 1975) and 42 C.F.R. Ch. IV (10-1-89 Edition), at 250-1 & n. 1. Brief, p. 7 n. 3. Although they point out the Weinberger case was dismissed on the condition that the admission review requirements be revised, they

fail to amplify that to date the admission review requirements contained in 42 C.F.R. Ch. IV are still in the process of being revised. Thus, currently, the federal regulations the Respondents point to remain ineffective. See 42 C.F.R. Ch. IV (10-1-92 Edition) at 274 n. 1.

In any event, the lawfulness of preadmission screening under the Medicare and Medicaid programs is not the issue presented for review. Rather, the issue is whether the regulations governing the Massachusetts preadmission screening program for chronic disease and rehabilitation hospitals violate 42 U.S.C. §1396b(i)(4) by applying procedures and standards which are

inconsistent with those applied under the Medicare program.[6]

C. The Preadmission Screening Program and Level of Care Criteria Conflict With Utilization Review Standards and Procedures Applied Under the Medicare Program.

The Respondents' attempt to convince this Court that the level of care criteria are consistent with the standards applied under the Medicare program is misleading. First, contrary to the Respondents' assertion, Brief,

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[6] The fact that 106 CMR §435.401(B)(3) provides that "a final determination of non-coverage will be made only by a physician" misses the point. The physician is constrained by the regulations to make his/her decision based on level of care criteria which conflict with the standards applied under the Medicare program.

p. 3, the affidavits[7] submitted by the Petitioners do not state that Peer Review Organizations ("PROs") "base" their determinations of medical necessity of inpatient hospital admissions on the application of the Adult Appropriateness Evaluation Protocol ("AEP"). Rather, the affidavits attest that the AEP is merely "one component" of the Medicare utilization review process. (R.A. 93,

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[7] Contrary to the Respondents' assertion, Brief p. 4, n. 2, the physicians' affidavits are based on factual matters within the affiants' knowledge. Seven physicians attested that the hospitals at which they practiced followed the Medicare utilization review process. R.A. 92, 98, 107, 118, 128, 138, 142. Six physicians were on their hospitals' utilization review committees; the other was past president of his hospital's utilization review committee. Id. In addition, two of the physicians served as physician reviewers for MassPRO, the federally designated Massachusetts Peer Review Organization. 42 U.S.C. 1320c-2(b)(2). R.A. 118, 128.

99, 108, 119, 129, 139, 142, 180). Issues regarding physician assessment of patient safety, medical instability, quality assurance and availability of resources in the community are other components. Id.[8]

The Respondents' reliance on articles in medical journals is misplaced. The articles describe the use of the AEP to determine the appropriateness of an acute hospital admission not a chronic hospital admission. This is because the AEP has not been found to be a valid instrument by which to measure the need for chronic hospital level of care. R.A. 212.

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[8] An affidavit submitted by Mehbooba Anwar, M.D., who is board certified in utilization review and quality assurance and serves as a physician reviewer for MassPRO, which describes the use of the AEP in the utilization review process is reproduced in the Appendix (infra, pp. A-1 - A-12).

Second, the Respondents' reference to §435.409(A) (1) and (2) underscores the problem which arises when a state Medicaid program fails to follow federal Medicare utilization review requirements. Under §435.409(A)(1)(c) patients who do not require "daily or more frequent physician supervision" or "the constant availability of medical services and equipment ordinarily available only in a hospital" are disqualified from hospital admission. There are some patients who may not require daily or more frequent supervision but for whom hospitalization would be deemed medically necessary under Medicare standards. R.A. 140. However, if these patients are admitted to nursing homes, they will receive only monthly physician visits absent an emergency. See 130 CMR 433.416(B) (payment for physician visits to

Medicaid patients in nursing homes limited to one visit per month). Appendix, infra, p. A-13.

Finally, the Respondents refer to the so-called "catch-all alternative" under §435.409(A)(2). Brief, pp. 17-18. The Respondents fail to point out that whether a recipient falls within the "catch-all alternative" is to be determined by "the clinical staff of the Department's medical case management program", not the hospital's utilization review committee.

CONCLUSION

For the foregoing reasons and the reasons stated in the Petition for a Writ of Certiorari, the Petition should be granted.

Respectfully submitted,

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Dated: February 1, 1994

APPENDIX

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, SS. SUPERIOR COURT
DEPARTMENT OF THE
TRIAL COURT

CIVIL ACTION
NO. 2553-93

JEWISH MEMORIAL HOSPITAL, et al.

Plaintiffs

vs.

DEPARTMENT OF PUBLIC WELFARE, et al.

Defendants

AFFIDAVIT OF
MEHBOOBA ANWAR, M.D. IN
SUPPORT OF PRELIMINARY INJUNCTION

I, Mehbooba Anwar, M.D., hereby depose and state that the following is true and based upon my personal knowledge.

1. I am a physician duly licensed to practice medicine within the Commonwealth of Massachusetts. I

currently serve as Medical Director of Massachusetts Respiratory Hospital and am responsible for medical care provided at the Hospital. I also serve as the Chairperson of the Hospital's Utilization Review Committee. I am board certified in utilization and quality assurance. I also serve as a Physician Reviewer for "MASS PRO" a federally established program for utilization review and quality assurance for medical care provided for Medicare patients.

2. I have reviewed the regulations governing the medical necessity of services provided by chronic disease and rehabilitation hospitals scheduled to be implemented on December 1, 1990 by the Department of Public Welfare. Attached hereto is [sic] Exhibit A is a true and accurate copy of that draft.

3. Massachusetts Respiratory Hospital follows the Medicare guidelines of the utilization review process to determine the medical necessity of patient admissions and the appropriateness, including safety of patient discharges. Similar process is followed for Medicaid patients. The Adult Appropriateness Evaluation Protocol ("AEP") is used as one of the components on admission by utilization review nurses to approve the admission as meeting the criteria but when and if "AEP" criteria are not met the care [sic] is reviewed by a U/R physician for the patient's medical condition, safety, quality assurance and availability of resources within the community prior to making a decision for denial. The attending physician and U/R physician takes unto consideration the potential for medical instability and for safety

and therefore may override "AEP" criteria. It is the responsibility of the attending physician and U/R physicians to apply their experience and medical knowledge in determining any potential for harm. The Department of Public Welfare's strict application of "AEP" criteria without incorporation of medical judgements will lead to admission denials and subject such patients to discharge procedures with serious potential for harm to patients due to inappropriate management.

4. Section 435.409 of the proposed regulations ignores the fact that under Medicare, the "AEP" may not be used by nurses, physicians or anyone else to deny admissions. Only a physician may deny an admission. Furthermore, under the Medicare process, only a peer of the attending physician may deny payment for an admission deemed

appropriate by the attending physician and such a denial may take place only after two levels of review have been provided, and even then additional appeal rights exist. The notice and appeal provisions set forth under Section 435.409(B) of the proposed regulations do not provide for such review. There is no requirement that the physician reviewer be a true peer of the attending physician.

5. I understand that the proposed regulations at 106 CMR 435.409 also apply to rehabilitation units in chronic disease hospitals. However, the "AEP" does not have rehabilitation guidelines. Therefore, it is inappropriate (and makes no sense) to apply the "AEP" to rehabilitation patients.

6. I have read 106 CMR 435.411 which requires that a review of each admission and continued stay be

conducted in accordance with Sections 435.409 and 435.410. What this means to me is that the "AEP" applies to patients at chronic disease and rehabilitation hospitals not only on admissions but also on continued stay review and on conversion. Under the Medicare program, the "AEP" is not used for conversions and is only one of a number of components used for continued stay review. In my experience at Massachusetts Respiratory Hospital, at any given point in time after admission, approximately 50% of the patients might not meet the "AEP" on a continual basis. Moreover, in my experience as a Mass Pro Review Physician, patients do not meet the "AEP" on a continual basis. The DPW is therefore proposing a level of care standard for chronic disease and rehabilitation hospitals that is even more stringent than the level of care

standard applied to acute hospitals. If implemented the regulation will directly interfere with my ability to admit and continue to treat patients.

7. The DPW's proposed regulations direct hospital physicians, including myself, to use the "AEP" to disqualify patients from continued hospital level of care. Patients not meeting the "AEP" are subject to discharge. Under the DPW's proposed regulations, I am also directed to deny admission and therefore, hospital services, to any patient who does not meet the "AEP".

8. One facet of the proposed regulation (106 CMR 435.409(A)(3)) requires that in order for hospital care to be medically necessary a patient must require daily physician services. By regulation 106 CMR 433.416(B), the DPW limits payment for physician visits to nursing home patients to one visit per

month, except in cases of an emergency. Therefore, patients at the Massachusetts Respiratory Hospital who are disqualified from hospital care because they do not meet the AEP on a continual basis (and/or do not require daily physician services) will generally only receive monthly physician visits in a nursing home. Various classes of patients subject to transfer clearly require more than monthly physician visits and may die before a nursing home staff knows the patient is in a medical crisis. Examples of these patients are: those who suffer from congestive heart failure with changes in weight due to fluid retention; those who have brittle diabetes with blood sugars varying from 50 to 400. Such patients are likely to have other unstable medical conditions and to require ongoing physician monitoring of multiple medications and

metabolic abnormalities. If such patients were discharged to nursing homes, they would predictably medically deteriorate rapidly, and among other things, experience pain, develop pneumonia, urinary infections and infectious sores. It is a medical fact that the foregoing will increase patient morbidity.

9. There are also classes of patients who would not meet the AEP on a continual basis who should not be discharged to nursing homes because the care which they require is not available there. These patients include those requiring IV fluids on a regular basis, those requiring inhaled bronchodilator treatment, and those whose pulmonary care requires medication and tracheostomy care with frequent suctioning. In my experience none of

these services are customarily and usually available in nursing homes.

10. Patients suffering from severe chronic obstructive pulmonary diseases require close medical and nursing monitoring to prevent deterioration and immediate availability of respiratory therapists to provide inhaled bronchodilator treatments. Patients with tracheostomies require frequent suctioning and assessment. The above types of patients may not meet "AEP" criteria on a continual basis. Therefore discharging these patients to inappropriate settings will cause deterioration and death. In my experience these services are not available in nursing homes. Under the Medicare program these patients meet the criteria of covered hospital level of care.

11. In view of the foregoing, the Department of Public Welfare's proposed regulations demand me to discriminate against Medicaid patients, which in my judgment interferes with my right to practice medicine in a standard and safe manner.

12. The Department of Public Welfare proposed a contract to implement the regulation which requires the Hospital to assist in hearings should a patient object to an application of the AEP. This means that Hospital medical staff would be required to testify against patients including those seeking admission. I object to this requirement. The medical staff cannot be placed in the position of acting contrary to the best interests of patients.

Signed and sworn to under the pains and penalties of perjury.

_____

Mehbooba Anwar, M.D.

Dated: November 21, 1990

433.416: Nursing Facility Visits: Service Limitations

(B) Service Limitations. Payment for a visit by a physician to recipients in nursing facilities or rest homes is limited to one visit per recipient per month, except in an emergency. Any medically necessary care required for the follow-up of a condition during the month must be billed as subsequent nursing facility care.